I. Introduction

With the cancellation of claims 5 and 35 herein without prejudice, claims 1-4, 6-8, 10-34, 36-58 and 60-82 are pending in the present application. In view of the foregoing amendments and the following remarks, it is respectfully submitted that all of the presently pending claims are allowable, and reconsideration is respectfully requested.

II. Rejection of Claims 29-32, 35-64 and 67-82 Under 35 U.S.C. § 102(b)

Claims 29-32, 35-64 and 67-82 were rejected under 35 U.S.C. 102(b) as anticipated by International Patent Publication No. WO93/15648 ("Wilk et al."). Applicant respectfully submits that Wilk et al. do not anticipate the present claims for the following reasons. As an initial matter, claim 59 was previously canceled without prejudice and claim 35 is herein canceled without prejudice; therefore, Applicant respectfully submits that the rejection of claims 35 and 59 is moot.

Claim 29 relates to a surgical system that includes a shaft having a distal end and a proximal end. Claim 29 has been amended herein without prejudice to recite that an interior of the shaft has a fluid-tight seal from the environment at the distal and proximal ends so as to be sterilizable for re-use. Support for this amendment can be found, for instance at page 5, lines 6-8 of the Specification which states that "[a]ccording to one embodiment, the shaft 12 includes a tubular sheath 13, which may include a coating or other sealing arrangement to provide a fluid-tight seal between ***an interior region*** of the shaft 12 ***and the environment***." Emphasis added.

Providing further support for the fluid-tight seal at the proximal end of the shaft, the Specification provides at page 5, lines 15-18 that "[o]ther suitable materials and sealing arrangements that may be employed are described in further detail in Applicants' co-pending U.S. Patent Application Ser. No. 10/099,634, filed on Mar. 15, 2002, which is expressly incorporated herein by reference in its entirety." This application, a copy of which is provided as U.S. Patent Application Publication No. 2004/0111081 in an Information Disclosure Statement filed herewith, discloses a flexible shaft 20, see, e.g., paragraph 0060, that employs "fluid-tight seal[s] between the interior of first coupling 22 and the environment." Paragraph 0063. Referring, for

example, to Figure 1, it is clear that this coupling is at the proximal end of the flexible shaft.

Claim 29 also recites that the surgical system includes an image capture device configured to receive image data from the distal end of the shaft. Claim 29 also recites that the surgical system includes a light source configured to provide light at the distal end of the shaft. Claim 29 has been amended herein without prejudice to recite that the image capture device and the light source are mounted ***at the distal end of the shaft*** and sealed from the environment so as to be sterilizable for re-use. Support for this amendment can be found, for instance at page 6, lines 8-10 of the Specification which states that "[a]dvantageously, the light source 26 and the image capture device 28 are sealed within the distal end 12a of the shaft 12 such that the light source 26 and the image capture device 28 are also sterilizable, e.g., autoclavable."

Claim 56 relates to a surgical system including a shaft having a proximal end and a distal end. Claim 56 has been amended herein without prejudice to recite that an interior of the shaft has a fluid-tight seal from the environment at the distal and proximal ends so as to be sterilizable for re-use. Support for this amendment can be found, for instance at page 5, lines 6-8 of the Specification which states that "[a]ccording to one embodiment, the shaft 12 includes a tubular sheath 13, which may include a coating or other sealing arrangement to provide a fluid-tight seal between ***an interior region*** of the shaft 12 ***and the environment***." Emphasis added. Additional support for the proximal fluid-tight seal may be found, for example at U.S. Patent Application Ser. No. 10/099,634, discussed in further detail above.

Claim 56 also recites that the surgical system includes an image capture device configured to receive image data from the distal end of the shaft. Claim 56 also recites that the surgical system includes a light source configured to provide light at the distal end of the shaft. Claim 56 recites that the surgical system includes a control module coupled to the proximal end of the shaft. Claim 56 recites that the surgical system includes a power module coupled to the control module, the power module configured to drive at least one drivable component housed in at least one of the shaft, the control module and the power module. Claim 56 recites that the surgical system includes at least one power source integrally housed in at least one of the shaft, the control module and the power module. Claim 56 has been amended

herein without prejudice to recite that the image capture device and the light source are mounted ***at the distal end of the shaft*** and sealed from the environment so as to be sterilizable for re-use. Support for this amendment can be found, for instance at page 6, lines 8-10 of the Specification which states that "[a]dvantageously, the light source 26 and the image capture device 28 are sealed within the distal end 12a of the shaft 12 such that the light source 26 and the image capture device 28 are also sterilizable, e.g., autoclavable."

Wilk et al. purport to describe "an endoscope with a disposable insertion member." Title. Wilk et al. state that "Fig. 1 [illustrates] an endoscope [that] comprises a hand held control module 12 and a disposable insertion tube 14 provided with a plurality of ducts or channels 16 extending longitudinally through the insertion tube to a distal end 18 thereof." Page 7, lines 5-8. Wilk et al. describe that "insertion tube 14 is slid over optical guide member 20 and attached to control module 12." Page 8, lines 33-35.

It is respectfully submitted that Wilk et al. do not anticipate claims 29 and 56 for at least the reason that Wilk et al. do not disclose, or even suggest, all of the features recited in claims 29 and 56. For example, Wilk et al. do not disclose, or even suggest, that an interior of a shaft has a fluid-tight seal from the environment at distal and proximal ends so as to be sterilizable for re-use, wherein an image capture device and a light source are mounted at a distal end of the shaft and sealed from the environment so as to be sterilizable for re-use as recited in claims 29 and 56. The Specification states at page 5, lines 6-8, that "[a]ccording to one embodiment, the shaft 12 includes a tubular sheath 13, which may include a coating or other sealing arrangement to provide a fluid-tight seal between an interior region of the shaft 12 and the environment." The Specification also states at page 5, lines 8-10, that "[t]he sheath 13 may be formed of a tissue-compatible, sterilizable elastomeric material [and] preferably, the sheath 13 may be formed of a material that is autoclavable." The Specification states at page 6, lines 8-10 that "[a]dvantageously, the light source 26 and the image capture device 28 are sealed within the distal end 12a of the shaft 12 such that the light source 26 and the image capture device 28 are also sterilizable, e.g., autoclavable." In describing the disadvantages of conventional endoscopic arrangements, the Specification states at page 21, lines 13-16, that "[c]onventional endoscopes typically can not be sterilized prior to use within a patient

because the materials employed in the manufacture of conventional endoscopes are not sterilizable, and because conventional endoscope are typically not adequately sealed to withstand a sterilization process." Emphasis added. In describing the advantages of the present invention, the Specification states at page 21, lines 21-26, that "because ... the shaft 12... may be sterilizable, [it] can be used more than once and on more than one patient, providing significant cost savings as compared to conventional endoscope systems that must be discarded after one use."

There is no disclosure or suggestion whatsoever in Wilk et al. that an image capture device and a light source are mounted at a distal and of a shaft and sealed from the environment so as to be sterilizable for re-use. Wilk et al. state that "[a]s further illustrated in Fig. 1, fiber optic bundle 22 is operatively connected at a proximal end to a charge coupled device ("CCD") 30 mounted to control module 12." Page 7. Furthermore, Wilk et al. state that "a light source 34 is operatively connected to control module 12 via a line 36." Page 8. Wilk et al. state that "[a] flexible optical guide member 20 is permanently connected at a proximal end to control module 12 and is slidably inserted into insertion tube 14." Page 7. Thus, as an initial matter, neither the image capture device 30 nor the light source 34 are described as being sealed from the environment so as to be sterilizable for re-use. On the contrary, the main purpose of Wilk et al. is to **avoid** sterilizing the endoscope, e.g., including the image capture device 30 and the light source 34. Wilk et al. describe at page 9, lines 1-4, that "[u]pon the termination of the operation, insertion tube 14 and optical guide member 20 are withdrawn from the patient [,] insertion tube 14 is then detached from control module 12 and optical guide member 20 is removed from insertion tube 14." Wilk et al. state at page 9, lines 5-7, that "[i]nsertion tube 14 is discarded, while control module 12 and optical guide member 20 are ready for immediate use with **another** disposable insertion tube 14." Emphasis added.

Also, Wilk et al. explicitly describe that the optical guide member 20, which is described as being "permanently connected at a proximal end to control module 12," is covered by a new, disposable insertion tube 14 after each use. The purpose of having a new disposable insertion tube 14 cover the optical guide member 20 after each use is to avoid the need for sterilizing endoscope, e.g., including the image capture device 30 and the light source 34 for re-use. Wilk et al. explicitly state this to be the case. For example, Wilk et al. state at page 9, lines 7-

10, that **"[t]here is no need to subject optical guide member 20 to sterilizing and cleaning operations which may damage the optical guide and eventually wear it down**." Emphasis added.

The Final Office Action states that "[k]eeping the optical guide member in a sterile condition (while the device is inside a body) would inherently require the material making up the outside of the tube to be "fluid-tight", if not "air-tight." Final Office Action at page 4. Applicant respectfully maintains that the Final Office Action's implication that the entire endoscope must therefore be fluid- and/or air-tight is misguided. Only the distal end of the endoscope, e.g., that portion that is covered by the insertion tube 14, is suitable to be inserted into a patient's body. Neither the control module 12, nor any of the proximally disposed components, e.g., the CCD 30, the light source 34, etc., is described as being, nor is suitable for, insertion into the patient's body. On the contrary, **the mere fact that Wilk et al. admits that the optical guide may be damaged or may eventually wear down if subjected to sterilization evidences that the optical guide member 20, and the image capture device 30 and the light source 34 that are permanently attached thereto, are not sealed at so as to be sterilizable for reuse**. If the image capture device 30 and the light source 34 were sealed so as to be sterilizable for reuse, then such damage would not occur. The present application states as much. For example, the Specification states at page 21, lines 13-16, that "[c]onventional endoscopes typically can not be sterilized prior to use within a patient because the materials employed in the manufacture of conventional endoscopes are not sterilizable, and because conventional endoscope are typically not adequately sealed to withstand a sterilization process." Emphasis added.

Also, **there is no disclosure or suggestion whatsoever in Wilk et al. that the proximal end of a shaft may have a fluid-tight seal from the environment**. Wilk et al. purports to describe a sealing arrangement at the distal end of a shaft. For example, Wilk et al. state at page 5, lines 24-26, that "the insertion tube includes a channel for receiving the optical guide member, the channel being closed at the **distal** end of the insertion tube." Emphasis added. With respect to the proximal end of the insertion tube, Wilk et al. describe at page 2, lines 1-6, "[a]n endoscope [that includes] a hand held control module, a flexible optical guide member ... connected at a proximal end to the control module, and a disposable insertion tube **removably attached** at a proximal end to the control module."

Emphasis added. Wilk et al. further state that "[t]he proximal end of the insertion tube 14 may be provided with a **lip 50** or other coupling element for removably connecting insertion tube 14 to control module 12." Emphasis added. As shown in Figure 1, the lip 50 does not provide a fluid-tight seal from the environment at the proximal end of the insertion tube 14.

Furthermore, **there is no disclosure or suggestion whatsoever in Wilk et al. that an interior of a shaft may have a fluid-tight seal from the environment at distal and proximal ends so as to be sterilizable for re-use**. On the contrary, the main purpose of Wilk et al. is to **avoid** sterilizing the endoscope, including the shaft. As set forth above, Wilk et al. describe at page 9, lines 1-4, that "[u]pon the termination of the operation, insertion tube 14 and optical guide member 20 are withdrawn from the patient [,] insertion tube 14 is then detached from control module 12 and optical guide member 20 is removed from insertion tube 14." Wilk et al. also state at page 9, lines 5-7, that "[i]nsertion tube 14 is discarded, while control module 12 and optical guide member 20 are ready for immediate use with **another** disposable insertion tube 14." Emphasis added. Thus, as an initial matter, Wilk et al. explicitly state that the insertion tube 14 is discarded after a single use, and therefore readily admit that the insertion tube 14 is not sterilized at all. Thus, it should be evident that the insertion tube 14 of Wilk et al. does not constitute the claimed shaft.

Also, Wilk et al. explicitly describe that the optical guide member 20 is covered by a new, disposable insertion tube 14 after each use. The purpose of having a new disposable insertion tube 14 cover the optical guide member 20 after each use is to avoid the need for sterilizing the optical guide member 20 for re-use. Wilk et al. explicitly state this to be the case. For example, Wilk et al. state at page 9, lines 7-10, that **"[t]here is no need to subject optical guide member 20 to sterilizing and cleaning operations which may damage the optical guide and eventually wear it down**." Emphasis added. **The mere fact that Wilk et al. admits that the optical guide may be damaged or may eventually wear down if subjected to sterilization evidences that an interior of the optical guide member 20 is not sealed from the environment at its proximal and distal ends so as to be sterilizable for reuse**. If the optical guide member 20 were sealed at its proximal and distal ends so as to be sterilizable for reuse, then such damage would not occur. The present application states as much. For example, the Specification

states at page 21, lines 13-16, that "[c]onventional endoscopes typically can not be sterilized prior to use within a patient because the materials employed in the manufacture of conventional endoscopes are not sterilizable, and because conventional endoscope are typically not adequately sealed to withstand a sterilization process." Emphasis added.

To anticipate a claim, each and every element as set forth in the claim must be found in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of Calif., 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Furthermore, "[t]he identical invention must be shown in as complete detail as is contained in the . . . claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). That is, the prior art must describe the elements arranged as required by the claims. In re Bond, 910 F.2d 831, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990). As more fully set forth above, it is respectfully submitted that Wilk et al. does not anticipate claims 29 and 56, because Wilk et al. does not disclose, or even suggest, all of the features recited in these claims.

In summary, it is respectfully submitted that Wilk et al. do not anticipate claims 29 and 56. As for claims 30-32, 36-55, 57, 58, 60-64 and 67-82, each of which ultimately depend from and include all of the limitations of a respective one of independent claims 29 and 56, it is respectfully submitted that Wilk et al. do not anticipate these dependent claims for at least the same reasons given above in support of the patentability of their respective independent claims.

III. Rejection of Claims 1-8, 10-28, 33, 34, 65 and 66 Under 35 U.S.C. § 103(a)

Claims 1-8, 10-28, 33, 34, 65 and 66 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Wilk et al. in view of Kanno et al. It is respectfully submitted that the combination of Wilk et al. and Kanno et al. does not render obvious the present claims herein for the following reasons. As an initial matter, claim 5 is herein canceled without prejudice; therefore, Applicant respectfully submits that the rejection of claim 5 is moot.

Claim 1 relates to a surgical system. Claim 1 recites that the surgical system includes a shaft having a distal end and a proximal end. Claim 1 has been amended herein without prejudice to recite that an interior of the shaft has a fluid-tight seal from the environment at the distal and proximal ends so as to be

sterilizable for re-use. Support for this amendment can be found, for instance at page 5, lines 6-8 of the Specification which states that "[a]ccording to one embodiment, the shaft 12 includes a tubular sheath 13, which may include a coating or other sealing arrangement to provide a fluid-tight seal between ***an interior region of the shaft 12 and the environment***." Emphasis added. Additional support for the proximal fluid-tight seal may be found, for example at U.S. Patent Application Ser. No. 10/099,634, discussed in further detail above. Claim 1 also recites that the surgical system includes an image capture device configured to receive image data from the distal end of the shaft. Claim 1 also recites that the surgical system includes a light source configured to provide light at the distal end of the shaft, wherein the light source is a light-emitting diode. Claim 1 has been amended herein without prejudice to recite that the image capture device and the light source are mounted ***at the distal end of the shaft*** and sealed from the environment so as to be sterilizable for re-use. Support for this amendment can be found, for instance at page 6, lines 8-10 of the Specification which states that "[a]dvantageously, the light source 26 and the image capture device 28 are sealed within the distal end 12a of the shaft 12 such that the light source 26 and the image capture device 28 are also sterilizable, e.g., autoclavable."

In rejecting a claim under 35 U.S.C. § 103(a), the Examiner bears the initial burden of presenting a prima facie case of obviousness. In re Rijckaert, 9 F.3d 1531, 1532, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). To establish prima facie obviousness, three criteria must be satisfied. First, there must be some suggestion or motivation to modify or combine reference teachings. In re Fine, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). This teaching or suggestion to make the claimed combination must be found in the prior art and not based on the application disclosure. In re Vaeck, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). Second, there must be a reasonable expectation of success. In re Merck & Co., Inc., 800 F.2d 1091, 231 U.S.P.Q. 375 (Fed. Cir. 1986). Third, the prior art reference(s) must teach or suggest all of the claim limitations. In re Royka, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974).

It is respectfully submitted that Wilk et al. do not anticipate claim 1, nor claims 29 and 56, from which claims 33, 34, 65 and 66 depend, for at least the reason that Wilk et al. do not disclose, or even suggest, all of the features recited in

claims 1, 29 and 56. For example, Wilk et al. do not disclose, or even suggest, that an interior of a shaft has a fluid-tight seal from the environment at distal and proximal ends so as to be sterilizable for re-use, wherein an image capture device and a light source are mounted at the distal end of a shaft and sealed from the environment so as to be sterilizable for re-use as recited in claims 1, 29 and 56.

There is no disclosure or suggestion whatsoever in either Wilk et al. or Kanno et al. that an image capture device and a light source are mounted at a distal end of a shaft and sealed from the environment so as to be sterilizable for re-use. As set forth above, Wilk et al. state that "[a]s further illustrated in Fig. 1, fiber optic bundle 22 is operatively connected at a proximal end to a charge coupled device ("CCD") 30 mounted to control module 12." Page 7. Furthermore, Wilk et al. state that "a light source 34 is operatively connected to control module 12 via a line 36." Page 8. Wilk et al. state that "[a] flexible optical guide member 20 is permanently connected at a proximal end to control module 12 and is slidably inserted into insertion tube 14." Page 7. Thus, neither the image capture device 30 nor the light source 34 are described as being sealed from the environment so as to be sterilizable for re-use, but rather the main purpose of Wilk et al. is to **avoid** sterilizing the endoscope, e.g., including the image capture device 30 and the light source 34. Also, Kanno et al. are not relied on to disclose or suggest, and do not disclose or suggest, that an image capture device and a light source are sealed from the environment so as to be sterilizable for re-use, which as set forth more fully above, is not disclosed or suggested by Wilk et al.

There is no disclosure or suggestion whatsoever in either Wilk et al. or Kanno et al. that a proximal end of a shaft may have a fluid-tight seal. As set forth above, Wilk et al. is directed to sealing at the distal end of the shaft, not at the proximal end of the insertion tube 14; rather, the lip 50 of Wilk et al. does not provide a fluid-tight seal at the proximal end of the insertion tube 14. Also, Kanno et al. describe an endoscopic light source apparatus 3A that can be selectively connected to an endoscope 1A. Kanno et al. state that "[a] flexible universal cord 13 is extended sidewise from the above mentioned operating part 12 and is provided at the tip with a connector 14 to be connected to the above mentioned light source apparatus 3A." There is no disclosure or suggestion whatsoever in Kanno et al. that the proximal end, e.g., connector 14, of the endoscope 1A has a fluid-tight seal.

Furthermore, **there is no disclosure or suggestion whatsoever in either Wilk et al. or Kanno et al. that an interior of the shaft may have a fluid-tight seal from the environment at its distal and proximal ends so as to be sterilizable for re-use**. As set forth above, the main purpose of Wilk et al. is to **avoid** sterilizing the endoscope, including the image capture device 30, the light source 34, and the shaft, e.g., the optical guide member 20, in that the insertion tube 14 is discarded after a single use, and the optical guide member 20 of the endoscope is covered by a new, disposable insertion tube 14 after each use precisely to avoid the need for sterilizing the optical guide member 20 for re-use. Also, Kanno et al. are not relied on to disclose or suggest, and do not disclose or suggest, a shaft that has a fluid-tight seal at distal and proximal ends so as to be sterilizable for re-use, which as set forth more fully above, is not disclosed or suggested by Wilk et al.

For at least the same reasons, the combination of Wilk et al. and Kanno et al. do not disclose, or even suggest, all of the limitations of claims 2-4, 6-8, 10-28, 33, 34, 65 and 66, because, by virtue of their dependency on a respective one of independent claims 1, 29 and 56, each one of these dependent claims includes the feature of a shaft that is sealed so as to be sterilizable for re-use. Therefore, it is respectfully maintained that claims 2-4, 6-8, 10-28, 33, 34, 65 and 66 are also allowable for at least the same reasons that claim 1, 29 and 56 are allowable as more fully set forth above. Withdrawal of this rejection is therefore respectfully requested.

III. Response to Comments Made in Advisory Action

In response to the Examiner's comments enclosed with the Advisory Action of January 22, 2007, Applicant maintains that the pending claims are allowable for the foregoing reasons. Specifically, the Advisory Action states:

> [T]he scope of at least claim 1 covers an image capture device and light source located in the control unit (e.g., not in the shaft), yet claim 1 recites that the image capture device and the light source are "sealed from the environment so as to be sterilizable for re-use." This raises an issue of at least claim 1 being too broad in

> scope to be supported by the specification since the specification does not appear to mention a proximally located image capture device and light source that is sealed from the environment.

Advisory Action at page 2. Applicant respectfully maintains that the amendment of claims 1, 29 and 56 to recite that the image capture device and the light source are mounted "at the distal end of the shaft and sealed from the environment so as to be sterilizable for re-use" is not too broad in scope to be supported by the Specification, as evidenced by the support identified hereinabove. In this regard, Applicant respectfully maintains that the current amendment renders moot the issue raised by the Examiner with regard to the scope of the independent claims.

IV. Conclusion

Applicant respectfully submits that the pending claims are in condition for allowance and requests that such action be taken. If for any reason the Examiner believes that prosecution of this application would be advanced by contact with the Applicant's attorney, the Examiner is invited to contact the undersigned at the telephone number given below.

Respectfully submitted,

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Date: March 27, 2007 By: _____

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